

### **DETAILED ACTION**

This is in response to the application filed on July 28, 2006 in which claims 1-34 are presented for examination.

#### ***Status of Claims***

Claims 1-34 are pending, of which 1 is in independent form. Claims 1, 2, 4, 5, 6 and 17 are rejected under 35 U.S.C. 102(b) and claims 3, 7-16, and 18-34 are rejected under 35 U.S.C. 103(a).

#### ***Claim Objections***

1. Claim 1 is objected to because of the following informalities: the recitation in line 4, "having an inner diameter which is smaller than the outer diameter of the stent when the tube is placed on the stent" is objected to because the inner diameter of the fabric tube is smaller than the outer diameter of the stent "prior" to the tube being placed on the stent and must be stretched to a larger inner diameter "when" the fabric tube is placed on the stent. Appropriate correction is required.

2. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 recites the same

limitation in claim 1 wherein the fabric tube has been manufactured with an inner diameter which is smaller than the outer diameter of the unexpanded stent.

***Claim Rejections - 35 USC § 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 2, 5-8, 15-17, and 19-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banas et al (US Patent No. 6,214,039) in view of Dong (US Patent No. 6,540,773).

Regarding claim 1, Banas et al or "Banas" herein, discloses a radially expandable endoluminal stent-graft assembly (10) including a tubular stent member or "stent" (12), an external surface of which is provided with a graft of expanded polytetrafluoroethylene (ePTFE), the graft being pre-formed into the shape of a tube (column 6, lines 36-38, FIG. 1, element #14), into which the stent has been placed in its unexpanded state, the graft member having an inner diameter that is smaller than the outer diameter of the stent is pre-expanded when the tube is axially placed over the stent resulting in an inward gripping action of the graft on the unexpanded stent wherein the graft member reduces until it meets with resistance to further recoil (column 7, lines

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7-16, column 10, lines 5-15). Banas fails to explicitly disclose the ePTFE graft to be fabric.

Regarding claim 2, Banas discloses a graft member (14) manufactured with an inner diameter which is smaller than the outer diameter of the unexpanded stent wherein the graft member has a pre-expanded diameter that is less than the unexpanded outer diameter of the stent member (column 7, lines 7-11, FIG. 5).

Regarding claim 5, Banas discloses an endoluminal stent-graft assembly or “stent assembly” (10) having a graft member (14) that is made of ePTFE (column 6, line 26).

Regarding claim 6, Banas discloses an endoluminal stent-graft assembly or “stent assembly” (10) having a graft member (14) made of expanded microporous polytetrafluoroethylene, i.e. a polymer (column 6, lines 21-23).

Regarding claim 7, Banas discloses an endoluminal stent-graft assembly or “stent assembly” (10) having a graft member (14) but fails to disclose the graft member made of a polymer selected from a group of polyurethane, polyamide, gelatine, silicone and agar.

Regarding claim 8, Banas discloses an endoluminal stent-graft assembly or “stent assembly” (10) having a graft member (14) but fails to disclose the fabric being made from a multifilament ePTFE yarn.

Regarding claim 15, Banas discloses an endoluminal stent-graft assembly or “stent assembly” (10) having a graft member (14) but fails to disclose stent having tubular elements aligned along a common longitudinal axis and successively joined together in pairs by respective sets of linking members.

Regarding claim 16, Banas discloses an endoluminal stent-graft assembly or “stent assembly” (10) having a graft member (14) but fails to disclose tubular elements existing essentially of a strip forming a zigzag corrugation.

Regarding claim 17, Banas discloses an endoluminal stent-graft assembly or “stent assembly” (10) wherein a graft member (14) completely covers the cylindrical external surface of the stent (column 6, lines 19-22, FIG. 1).

Regarding claim 19, Banas discloses an endoluminal stent-graft assembly or “stent assembly” (10) having a graft member (14) but fails to disclose an auto-expandable stent.

Regarding claim 20, Banas discloses an endoluminal stent-graft assembly or “stent assembly” (10) having a graft member (14) but fails to disclose a stent made essentially from a material selected from a group of stainless steel, Phynox®, and nitinol.

Regarding claim 21, Banas discloses a stent member or “stent” (12) that is expandable by the forced expansion of a balloon (column 11, lines 35-38, FIG. 1). However, Banas fails to disclose a stent made of a metallic material.

Regarding claim 22, Banas discloses an endoluminal stent-graft assembly or “stent assembly” (10) having a graft member (14) but fails to disclose the stent being made of metallic material selected from a group including tungsten, platinum, tantalum, gold, and stainless steel.

Dong teaches radially expandable stent-graft endoprosthesis or “stent assembly” (FIG. 1, element #10) including a stent (14) and a textile graft (12). The textile graft or “fabric tube” (12) is a knitted tubular graft made of a polymeric filamentary material that may be formed from a multifilament yarn of polytetrafluoroethylene or polyurethane (column 10, lines 4-13, FIG. 1). The stent (14) having tubular elements that are joined together by linking members (FIG. 7) or have a “zig zag” pattern (column 5, lines 59-64, FIG. 4). The stent (14) may be either self-expandable or expanded by force through the

use of a balloon. Stent (14) is may be made of the metallic materials nitinol, stainless steel, platinum or gold.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the polytetrafluoroethylene graft member of Banas with the multifilament woven graft member of Dong, for the predictable result of enhanced porosity and flexibility.

Further, Banas and Dong teach known devices, i.e. stents, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have substituted the stent of Banas with the various patterned stents of Dong for the predictable result of radial expansion and compression.

4. Claims 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banas et al (US Patent No. 6,214,039) in view Dong (US Patent No. 6,540,773), further in view of Slater et al (US Patent No. 5,522,883).

Regarding claim 3, the combination of Banas and Dong discloses all of the limitations previously discussed in claim 1 except for a fabric tube having a longitudinally folded smaller diameter than the outer diameter of the stent.

Slater et al teach a graft (32) having a compressed or folded shape which would permit radial expansion (column 4, lines 59-64).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the graft member of the combination of Banas and Dong with folds, as taught by Slater et al, for the predictable result of radial expandability of the graft member.

5. Claims 4, 14, 18 and 34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banas et al (US Patent No. 6,214,039) in view Dong (US Patent No. 6,540,773), further in view of Hoganson et al (US PGPub No. 2003/0074049A1).

Regarding claims 4 and 14, the combination of Banas and Dong discloses an endoluminal stent-graft assembly or “stent assembly” (10) wherein the desired porosity of the ePTFE fabric of the graft member or “fabric tube” (14) can be selected (column 10, lines 21-22, Dong) However, the combination of Banas and Dong fails to disclose storing drugs or liquid based drugs within the graft.

Regarding claim 18, the combination of Banas and Dong discloses an auto-expandable or balloon expandable stent but fails to explicitly disclose a stent that is crimped onto a balloon for expanding the stent.

Regarding claim 34, the combination of Banas and Dong discloses all of the limitations previously discussed in claim 1 except for a method step of providing a drug in the fabric.

Hoganson et al teach a covered stent having a stent body (20) that is encompassed by a cover (22) that can be made of polyurethane [0071]. Hoganson et al also teach a fabric with a porosity or “openness” [0079] wherein the cover or “fabric

tube" (22) is made of a combination of porous and non-porous layers into which therapeutic drugs or agents can be applied as coatings to the cover [0107]. Additionally, Hoganson et al teach a covered stent or "stent assembly" (FIG. 1, element #10) that can be crimped onto a balloon for expansion [0132]. Please see FIG. 1 and Table 1.

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to have made the graft of the combination of Banas and Dong with layers of varying porosity of polyurethane to be crimped onto a balloon for expansion, as taught by Hoganson et al because it was well known in the art to provide a fabric tube of non-resorbable polymer materials such as polyurethane to control the elasticity and inflation pressure of the graft and achieve low residual stress and to provide time-released therapeutic agents to prevent restenosis and thrombosis.

Further, it would have been obvious to have crimped the stent of the combination of Banas and Dong onto a balloon, as taught by Hoganson et al, for delivering the stent at a desired location.

6. Claims 23, 24, 32, and 33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banas et al (US Patent No. 6,214,039) in view Dong (US Patent No. 6,540,773), further in view of Orth et al (US Patent No. 5,591,197).

Regarding claim 23, the combination of Banas and Dong discloses a method of manufacturing an endoluminal stent-graft assembly or "stent assembly" (10) including the step of applying the graft member or "fabric tube" (14) to the stent (column 8, lines 44-56, Banas). Banas further discloses a tubular stent member or "stent" (12), an

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external surface of which is provided with a fabric of expanded polytetrafluoroethylene, the fabric (column 10, lines 5-12, Dong) has been pre-formed into the shape of a tube (column 6, lines 36-38, FIG. 1, element #14, Banas), into which the stent has been placed in its unexpanded state, the graft member or “fabric tube”, having an inner diameter which is smaller than the outer diameter of the stent, is pre-expanded when the tube is axially placed over the stent resulting in an inward gripping action of the fabric tube on the unexpanded stent wherein the graft member reduces until it meets with resistance to further recoil (column 7, lines 7-16, column 10, lines 5-15, Banas). Banas fails to disclose the step of manufacturing a stent.

Regarding claim 24, the combination of Banas and Dong discloses a method step wherein a graft member or “fabric tube” (14) is preformed with an inner diameter which is smaller than the outer diameter of the unexpanded stent (FIG. 5, elements #12 and #14, Banas) and the graft member has a pre-expanded diameter that is less than the unexpanded outer diameter of the stent member (column 7, lines 7-11, FIG. 5, Banas).

Regarding claim 32, the combination of Banas and Dong discloses all of the limitations previously discussed in claim 23 except for the step of manufacturing a stent from a hollow tube, in which a pattern of tubular elements and linking elements is formed.

Regarding claim 33, the combination of Banas and Dong discloses all of the limitations previously discussed in claim 23 except for the step of manufacturing a stent including rolling up a sheet of material to form the tube, and securing adjoining edge portions of the sheet together.

Orth et al teach an intravascular stent or “stent” (10) that can be made of metallic materials such as stainless steel, tungsten, platinum or gold (column 10, lines 14-16) and is balloon expandable or auto expandable by phase transition using memory-shaped alloys (column 9, lines 23-31). Orth et al also teach the manufacturing a stent from a flat sheet of material wherein the sheet is formed into a tube, the shape of a stent, or a sheet of stainless steel tubing in which laser cutting is performed to create a pattern of tubular elements and linking elements (column 10, lines 15-18, FIG. 1C). The Examiner notes, though Orth is silent as to how the edge portions of the sheet are secured it is well known in the art that a closure is formed by joining the edge portions of a sheet when making a tube.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the stent of the combination of Banas and Dong, utilizing the method steps of Orth, since it was well known in the art to construct slotted metallic stents using laser cutting.

The method steps of claims 23, 24, 32, and 33 have been rendered obvious by the above discussion.

7. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banas et al (US Patent No. 6,214,039), Dong (US Patent No. 6,540,773) and Orth et al (US Patent No. 5,591,197) as applied to claim 23, further in view of Slater et al (US Patent No. 5,522,883).

Regarding claim 25, the combination of Banas, Dong and Orth et al discloses all of the limitations previously discussed in claim 23 except for the method step of applying a fabric tube having longitudinal folding to an unexpanded stent.

Slater et al teach a graft (32) having a compressed or folded shape which would permit radial expansion (column 4, lines 59-64).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have provided the graft member of the combination of Banas, Dong and Orth et al, with folds, as taught by Slater et al, for the predictable result of radial expandability of the graft member.

The method steps of claim 25 are rendered obvious by the above discussion.

8. Claims 9-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banas et al (US Patent No. 6,214,039), Dong (US Patent No. 6,540,773), further in view of Ignatious et al (US PGPub No. 2003/0017208A1).

Regarding claim 9, the combination of Banas and Dong discloses all of the limitations previously discussed in claim 5 except for a portion of the fabric produced by spinning of nanofibers.

Regarding claim 10, the combination of Banas and Dong discloses all of the limitations previously discussed in claim 9 except for a portion produced by electrospinning.

Regarding claim 11, the combination of Banas and Dong discloses all of the limitations previously discussed in claim 9 except for a diameter of the nanofibers being in the range of 2 to 4000 nanometers, such as in the range of 2 to 3000 nanometers.

Regarding claim 12, the combination of Banas and Dong discloses all of the limitations previously discussed in claim 9 except for having nanofibers made from a polymer.

Regarding claim 13, the combination of Banas and Dong discloses all of the limitations previously discussed in claim 12 except for having nanofibers made from a material selected from a group including nylon, fluoropolymers, polyolefins, polyimides, and polyesters.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the graft member of the combination of Banas and Dong by electrospinning, as taught by Ignatious, since it was well known in the art to construct a PTFE graft by electrospinning.

9. Claims 26-28, 30, and 31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Banas et al (US Patent No. 6,214,039), Dong (US Patent No. 6,540,773) and Orth et al (US Patent No. 5,591,197), as applied to claim 23, further in view of Ignatious et al (US PGPub No. 2003/0017208A1).

Regarding claim 26, the combination of Banas, Dong and Orth et al discloses all of the limitations previously discussed in claim 23 except for the fabric being manufactured by spinning of nanofibers

Regarding claim 27, the combination of Banas, Dong and Orth et al discloses all of the limitations previously discussed in claim 23 except for manufacturing fibers using electrospinning

Regarding claim 28, the combination of Banas, Dong and Orth et al discloses all of the limitations previously discussed in claim 23 except for a diameter of the nanofibers in the range of 2 to 4000 nanometers.

Regarding claim 30, the combination of Banas, Dong and Orth et al discloses all of the limitations previously discussed in claim 23 except for having nanofibers made from a polymer.

Regarding claim 31, the combination of Banas, Dong and Orth et al discloses all of the limitations previously discussed in claim 30 except for having nanofibers made from a material selected from a group including nylon, fluoropolymers, polyolefins, polyimides, and polyesters.

Ignatious et al teach applications, i.e. vascular grafts, for the use of electrospun nanofibers wherein the polymeric fibers have diameters of 100 nanometers, within the range of 2 to 3000 nanometers [0031], made from the fluoropolymer, polytetrafluoroethylene (PTFE) [0054]. Ignatious et al further teach the incorporation of drugs dispersed within nanofibers [0036].

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have constructed the graft member of the combination of Banas, Dong and Orth et al by electrospinning, as taught by Ignatious, since it was well known in the art to construct a PTFE graft by electrospinning.

The method steps of claims 26, 27, 28, 30, and 31 are rendered obvious by the above discussion.

10. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Banas et al (US Patent No. 6,214,039), Dong (US Patent No. 6,540,773), Orth et al (US Patent No. 5,591,197) and Ignatious et al (US PGPub No. 2003/0017208A1), as applied to claim 26, further in view of Reneker et al (US Patent No. 6,382,526).

Regarding claim 29, the combination of Banas, Dong, Orth and Ignatious discloses all of the limitations previously discussed in claim 26 except for the step of feeding a first fiber-forming material into a nozzle for forming nanofibers by using a pressurized gas stream, and ejecting the first fiber-forming material from an exit orifice of the nozzle in the form of a plurality of strands of first fiber-forming material that solidify and form nanofibers.

Reneker et al teach a process of producing nanofibers using the method steps of having a nozzle (10) and a source providing a fiber-forming material and feeding it through an annular space of the nozzle (13), forcing pressurized gas from a gas source (18) and ejecting strands from the outlet orifice (16) that will solidify and form nanofibers (column 4, lines 48-67, FIG. 1)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to have utilized the known technique of Reneker et al in the method of the combination of Banas, Dong, Orth et al and Ignatious for the predictable result of forming nanofibers while providing high porosity to a device in which the size and shape of the device change.

The method steps of claim 29 are rendered obvious by the above discussion.

### ***Conclusion***

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bley et al (US Patent No. 5,968,070) and Bornat (US Patent No. 4,323,525) are related to electrostatic spinning and covered stents.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOCELIN C. TANNER whose telephone number is (571)270-5202. The examiner can normally be reached on Monday through Thursday between 9am and 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Frantz Coby can be reached on 571-272-4017. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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